

CITROMA- magnesium citrate liquid

Vi-Jon, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Swan 166.000 166AA rev 1

Active Ingredient

Magnesium citrate 1.745g per fl oz

Purpose

Saline laxative

use

for relief of occasional constipation (irregularity). Generally produces bowel movement in 1/2 to 6 hours

Warnings

for this product

Ask A Doctor

before use if you have

- kidney disease
- a magnesium restricted diet
- abdominal pain, nausea, or vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks
- already used a laxative for a period longer than 1 week

Ask a doctor or pharmacist

before use if you are taking any other drug. Take this product 2 or more hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use

and ask a doctor if you have rectal bleeding or failure to have a bowel movement after use. These could be signs of a serious condition.

if pregnant or breast-feeding

ask help professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away

Store at temperatures between 46° and 86°F (8° and 30° C)

Directions

- shake well before using
- drink a full glass (8 ounces) of liquid with each dose
- may be taken as a single daily dose or in divided doses

adults and children 12 years of age and over - 6.5 to 10 fl oz in 24 hours

children 6 to under 12 years of age - 3 to 7 fl oz maximum 7 fl oz in 24 hours

children 2 to under 6 years of age - 2 to 3 fl oz in 24 hours

children under 2 years of age - ask a doctor

other information

- each fl oz contains: **magnesium 290 mg**
- each fl oz contains: **sodium 1 mg**

Inactive ingredients

benzoic acid, citric acid, disodium EDTA, flavor, sucralose, water

Adverse Reaction

Distributed by: Vi-Jon, LLC

One Swan Drive,

Smyrna, TN 37167

Principal Display Panel

SWAN

VERY LOW SODIUM

Citroma

MAGNESIUM CITRATE

Lemony

- Saline Laxative
- Oral Solution

Alcohol content 0.12% (from flavoring)

Do not use if tamper evident twist-off cap is missing, broken or separated from neckring

10 FL OZ (296 mL)



CITROMA

magnesium citrate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0869-0166
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM CITRATE (UNII: RHO26O1T9V) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CITRATE	1.745 g in 29.6 mL

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

BENZOIC ACID (UNII: 8SKN0B0MIM)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0869-0166-38	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	02/18/2018	

Labeler - Vi-Jon, LLC (790752542)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(0869-0166)

Revised: 4/2021

Vi-Jon, LLC